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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/824,625	04/02/2001	Albert S. Lee	22727-66	8907

21125 7590 10/21/2002

NUTTER MCCLENNEN & FISH LLP
WORLD TRADE CENTER WEST
155 SEAPORT BOULEVARD
BOSTON, MA 02210-2604

EXAMINER

SCHOPFER, KENNETH G

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 10/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/824,625

Applicant(s)

LEE ET AL.

Examiner

Kenneth G Schopfer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 20-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I and the first species, claims 1-19 in Paper No. 11 is acknowledged. The traversal is on the ground(s) that the inventions are all classified in class 607, subclass 113, and that a single search should suffice for examination of all pending claims. This is not found persuasive because the search of any one invention listed in the restriction requirement would not be the same as the search for another invention. There may be some overlap, but overall the searches would be different.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the tissue" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim. The preamble to the claim states that the apparatus is "for thermally affecting tissue." As worded, this is not a positive recitation of a tissue. Further, if the claim language were changed to positively recite a tissue, the claim would be rejected under 35 U.S.C. 101 as attempting to claim non-statutory subject matter. Claims 2-19 are necessarily rejected as being dependent on the rejected base claim 1.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-5, 7, 8, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Stenberg (USPN 4010795).

6. Referring to claims 1-5, 7, 8, and 19, Stenberg teaches all of the limitations of these claims. Stenberg teaches an apparatus for thermally affecting tissue including an implantable member 5 having an outer surface for contacting tissue and a fluid-tight lumen 8 configured to receive a cooling liquid. The implantable member has an oval coil shape and is formed from a flexible, heat conductive, and biocompatible material. Further, the implantable member can be placed in contact with epidural or subdural brain tissue. Finally, the implantable member is formed of shape memory material, formable metal wire 9 (column 2, lines 4-7).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 6, and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stenberg (USPN 4010795) in view of Daily (USPN 5609620).

9. Referring to claim 6, Stenberg teaches all of the limitations of this claim as described above except for the implantable member being formed from a silicone elastomer. Daily discloses an apparatus for thermally affecting tissue that may be formed from a silicone elastomer (column 3, line 18). It would have been obvious to one of ordinary skill in the art at the time of invention that the device of Stenberg could have been made from silicone as in the device of Daily as a suitable heat conductive and biocompatible material.

10. Referring to claims 9-11, Stenberg teaches all of the limitations of these claims as described above except for the backing member. Daily teaches an apparatus for thermally affecting tissue that includes a backing member 56 made of silicone that is in thermal contact with tissue and is inherently designed to resist adherence to tissue. It would have been obvious to one of ordinary skill in the art at the time of invention to include a backing member as in Daily in the device of Stenberg to provide the device with a flat thermal transmission surface.

11. Claims 12-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stenberg (USPN 4010795) in view of Goble et al. (USPN 5891134).

12. Referring to claims 12 and 13, Stenberg teaches all of the limitations of these claims as described above except for the temperature measurement element. Goble teaches an apparatus for thermally affecting tissue including a temperature measurement element 66 positioned in the fluid-tight lumen of the device and a temperature indication element in the control unit 14 for indicating the temperature of the thermally transmissive fluid of the device. It would have been

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obvious to one of ordinary skill in the art at the time of invention to include a temperature measurement system as in Goble et al. in the device of Stenberg in order to ensure that the device is working properly and that contacted tissue is not adversely affected by the temperature of the device.

13. Referring to claim 14, the combined device of Stenberg and Goble et al. teaches all of the limitations of this claim as described above except for the temperature measurement element being positioned between the implantable member and the tissue in order to indicate the temperature of the tissue. It would have been obvious to one of ordinary skill in the art at the time of invention that the temperature measurement element of the combined device of Stenberg and Goble et al. could have been placed between the implantable member and the tissue in order to monitor the temperature of the tissue so that it is not permanently harmed during a procedure.

14. Referring to claims 15-18, Stenberg teaches all of the limitations of these claims as described above except for the pressure measurement element. Goble et al. teach an apparatus for thermally affecting tissue including a pressure sensor 58 and pressure warning alarm 62 in order to ensure that the fluid pressure in the device does not adversely affect the device and surrounding tissue. It would have been obvious to one of ordinary skill in the art at the time of invention to include a pressure measurement element as in Goble et al. between the implantable member and the tissue in the device of Stenberg to ensure that the pressure exerted by the device does not harm surrounding tissue.

Conclusion

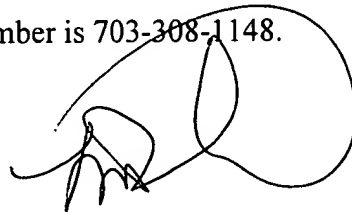
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth G Schopfer whose telephone number is 703-305-2649. The examiner can normally be reached on M-F (8:00-5:30) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 703-308-0994. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.

RB

KS
October 8, 2002



LINDA C. M. DVORAK
SUPERVISORY PATENT EXAMINER
GROUP 3700